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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/840,257	04/23/2001	Robert A. Scott	6512-11EJF	7160

29668 7590 01/26/2005

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EXAMINER	
HON, SOW FUN	
ART UNIT	**PAPER NUMBER**
1772	

DATE MAILED: 01/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/840,257	SCOTT ET AL.	
	Examiner	Art Unit	
	Sow-Fun Hon	1772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 November 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *57-61,63-65,67-71 and 73-81* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *57-61,63-65,67-71 and 73-81* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/09/04 has been entered.

Withdrawn Rejections

2. The 35 U.S.C. 102(b) and 103(a) rejections of claims 57-61, 63-65, 67-71, 73-81 have been withdrawn to Applicant's amendment dated 11/09/04.

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 57, 60-61, 67-70, 78-81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamamoto et al. (US 5,264,223) in view of Jansen (US 2,799,897).

Regarding claims 57, 81, Yamamoto teaches a capsule for pharmaceutical use (title). The capsule comprises a film-forming polymer (water-soluble cellulose derivative) and a setting (gelatinizing) agent (abstract). Yamamoto teaches that the setting agents are polysaccharide hydrocolloids such as kappa-carrageenan (column 3, lines 1-10) and the (auxiliary) cations listed (column 3, 10-20). Yamamoto teaches that the amount of film-forming polymer (water soluble

cellulose derivative) is 92 to 94 % by weight (column 4, lines 30-35), which is within the claimed range of 90 to 97 %, the amount of hydrocolloid (setting (gelatinizing) agent) is 0.1 to 0.5 % by weight, which is within the claimed range of 0.01 to 10 %, the amount of cation (auxiliary) is 0.01 to 0.5 % by weight (column 4, lines 25-35), which is within the claimed range of 0.001 to 5 %, and the amount of water is 4 to 6 % by weight of the capsule film (column 4, lines 35-40), which is within the claimed range of 2 to 7 %, in order to obtain a good hard capsule film via dip molding (conventional immersion molding method) (column 4, lines 15-20).

Yamamoto fails to teach that the film-forming polymer of the specific capsule composition is polyvinyl alcohol.

Jansen teaches a method for producing capsules (title), and that the encapsulating composition can be polyvinyl alcohol in place of cellulose derivatives (esters), and may be used to advantage in many applications (column 5, lines 50-60).

Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made, to have used polyvinyl alcohol as the film-forming polymer in place of the cellulose derivative of Yamamoto, in order to obtain a capsule with the physical properties of polyvinyl alcohol, as taught by Jansen.

Regarding claims 60-61, Yamamoto teaches the formation of the capsule by immersion of a moulding pin into a solution of the composition (column 4, lines 1-10). Although Yamamoto fails to teach that the capsule comprises two halves sealed together (claim 60) by a liquid fusion process (claim 61), the resultant capsule is still the same. Even though product by process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of

production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985).*

Regarding claim 67-70, Yamamoto teaches that the setting agents are polysaccharide hydrocolloids such as kappa-carrageenan (column 3, lines 1-10) and the (auxiliary) cations listed (column 3, 10-20). Other hydrocolloids taught are polysaccharides of tamarind seed (tamarind gum) and curdlan (column 3, lines 1-4).

Regarding claims 71, 73-77, Yamamoto teaches that plasticizer and coloring agent (dye or pigment) may be added to the capsule composition, as taught in the prior art (column 1, lines 15-20). Hence the amounts of plasticizer and coloring agent can be 0, which meet the lower end of the claimed range of from about 0 to 40 % plasticizer (claim 71) and the lower end of the claimed range of from about 0 to 10 % of coloring agent (claim 74).

Regarding claims 78-79, Yamamoto teaches a hard capsule (title) (claim 78). It would have been obvious to one of ordinary skill in the art at the time the invention was made, to have formed a soft capsule by varying the amounts of the components of the capsule composition of Yamamoto, in order to obtain a capsule that is soft for the desired end-use.

Regarding claim 80, Yamamoto teaches a method of manufacturing a capsule comprising a) forming an aqueous solution comprising 5 to 25 % by weight of film-forming cellulose derivative, which overlaps the claimed range of 10 to 60 %, 0.10 to 5 % by weight of setting agent (gelatinizing agent), which overlaps the claimed range of 0.10 to 5 % by weight and 0.01 to 0.5 % by weight of auxiliary for gelation (column 3, lines 20-30), which overlaps the claimed range of 0.001 to 3 %, and b) immersion molding (column 4, lines 1-10) which is the same as dip

molding, the aqueous solution to form the capsule. Yamamoto teaches that the setting agents are polysaccharide hydrocolloids such as kappa-carrageenan (column 3, lines 1-10) and the (auxiliary) cations listed (column 3, 10-20).

5. Claims 58-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamamoto in view of Jansen as applied to claims 57, 60-61, 67-70, 78-81 above, and further in view of Deters et al. (US 4,627,850).

Yamamoto in view of Jansen has been discussed above, and fails to teach that the capsule has at least one coating thereon.

Deters teaches a capsule with a first lamina 33 formed of polyvinyl alcohol (column 9, lines 25-30) which is a hydrophilic polymeric composition (column 5, lines 10-20), and coated (lamina 34 comprising a semipermeable polymeric composition) (column 8, lines 10-25). An example of the coating (lamina 34) is hydroxypropyl methylcellulose phthalate (column 8, lines 50-60). Deters teaches that the coating (second lamina) is for allowing the passage of fluid (permeable) and for preventing the passage of useful agent (impermeable) (column 1, lines 5-15) in order to allow the control of administration of useful agent during the capsule's residency in the environment of use over an extended period of time (column 2, lines 1-5).

Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made, to have coated the capsule of Yamamoto in view of Jansen, with hydroxypropyl methylcellulose phthalate, in order to obtain a capsule with the desired release characteristics, as taught by Deters.

Allowable Subject Matter

6. Claims 63-65 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The closest cited prior art of record, US 5,264,223 fails to teach, even in combination with US 2,799,897 and US 4,627,850, the combination of a capsule comprising 90 to 97 % by weight of a polyvinyl alcohol, 2 to 7 % by weight of water, a setting system comprising 0.01 to 10 % by weight of a hydrocolloid or mixtures thereof and a sequestering agent selected from the group consisting of ethylenediaminetetraacetic acid, acetic acid, boric acid, citric acid, edetic acid, gluconic acid, lactic acid, phosphoric acid, tartaric acid or salts thereof, metaphosphates, dihydroxyethylglycine, lecithin, beta cyclodextrin and combinations thereof, and 0.001 to 5 % by weight of cations, based on the total weight of the capsule.

Response to Arguments

7. Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication should be directed to Sow-Fun Hon whose telephone number (571)272-1492. The examiner can normally be reached Monday to Friday from 10:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon, can be reached on (571)272-1498. The fax phone number for the organization where this application or proceeding is assigned is (703)872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

S. Hon

Sow-Fun Hon

01/21/05

ARNOLD PYON
SUPERVISORY PATENT EXAMINER
1772

1/24/05